

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

JEFFERY CLINE,

Plaintiff,

v.

MEDTRONIC, INC.;
MEDTRONIC USA, INC.;
MEDTRONIC LOGISTICS, LLC; and
MEDTRONIC PUERTO RICO
OPERATIONS, CO.,

Defendants.

CIVIL ACTION FILE

JURY TRIAL DEMANDED

- 1) STRICT LIABILITY
MANUFACTURING DEFECT
- 2) STRICT LIABILITY FAILURE TO
WARN
- 3) BREACH OF IMPLIED
WARRANTY
- 4) PUNITIVE DAMAGES

COMPLAINT FOR DAMAGES

Plaintiff Jeffery Cline, by and through his attorneys, files this Complaint for Damages against Defendants, Medtronic, Inc.; Medtronic Puerto Rico Operations, Inc.; and Medtronic Logistics, LLC (collectively “Defendants” or “Medtronic”), as follows:

I. INTRODUCTION

1. This is a product liability action seeking damages for personal injuries sustained by Plaintiff Jeffery Cline arising from his use of a defective product designed, manufactured, labeled, distributed, and/or otherwise placed into the stream of commerce by Defendants and/or each of them. As set forth herein, Mr. Cline suffered severe injuries and hospitalization as a foreseeable, direct, and proximate result of defects in his Medtronic SynchroMed II Programmable Implantable Infusion Pump System for intrathecal drug delivery, which was implanted in his abdomen. Mr. Cline brings this action to recover for the damages caused by Defendants’ conduct.

II. PARTIES

2. Plaintiff Jeffery Cline is, and at all relevant times was, a citizen of Ohio and resident of Quaker City, Ohio.

3. Defendant Medtronic, Inc. is, and at all relevant times was, a corporation or other business entity and citizen of Minnesota, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432.

4. Defendant Medtronic USA, Inc. is, and at all relevant times was, a corporation or other business entity and citizen of Minnesota, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Anoka County, Minnesota 55432.

5. Defendant Medtronic Puerto Rico Operations Co. is, and at all relevant times was, a corporation or other business entity and a wholly owned subsidiary of Defendant Medtronic, Inc., and citizen of the Cayman Islands, with its principal place of business at Ceiba Norte Industrial Park Road 31, Km. 24, HM 4 Call Box 4070, Junco 00777-4070, Puerto Rico.

6. Defendant and Medtronic Logistics, LLC is, and at all relevant times was, a corporation or other business entity and a wholly owned subsidiary of Defendant Medtronic, Inc., and citizen of Minnesota, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. The sole member of Medtronic Logistics, LLC is, and at all relevant times was, Medtronic USA, Inc., a corporation or other business entity and citizen of Minnesota, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Anoka County, Minnesota 55432.

III. JURISDICTION AND VENUE

1. At all times relevant hereto, Defendants Medtronic, Inc.; Medtronic USA, Inc.; Medtronic Logistics, LLC; and Medtronic Puerto Rico Operations Co. (hereinafter collectively

referred to as “Defendants” or “Medtronic”) are and were involved in designing, assembling, manufacturing, testing, packaging, labeling, marketing, distributing, selling, promoting, and/or otherwise placing into the stream of commerce a medical device called the SynchroMed II Programmable Implantable Infusion Pump System (hereinafter referred to as the “SynchroMed II Device”).

2. This Court has personal jurisdiction over all Defendants pursuant to Ohio Rev. Stat. § 2307.382, under which a court in Ohio may exercise personal jurisdiction over a person who acts directly or by an agent, as to a cause of action arising from the person's transacting any business in Ohio, contracting to supply services or goods in Ohio, causing tortious injury by an act or omission outside this state if he regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered in Ohio, or causing injury in Ohio to any person by breach of warranty expressly or impliedly when he might reasonably have expected such person to use, consume, or be affected by the goods in Ohio, provided that he also regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered in Ohio.

3. Defendants meet one or more of these conditions, insofar as Defendants are, and all relevant times were, involved in the design, assembly, manufacture, testing, packaging, labeling, marketing, distribution, sale, and/or promotion of, and/or were otherwise involved in the placing in the stream of commerce, medical devices including the SynchroMed II Programmable Implantable Infusion Pump System (hereinafter the “SynchroMed II Device” or “Device”), and thus transacted business within Ohio; committed torts within Ohio as pled herein; and/or entered into a contract within Ohio.

4. This Court has diversity subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) because it is a civil action in which the matter in controversy exceeds the sum or value of \$75,000, exclusive of interests and costs, and is between citizens of different states and a foreign state.

5. Pursuant to Ohio state HB 197, the Statute of Limitations for this case has been tolled from March of 2020 to at least July 30, 2020.

IV. FACTUAL ALLEGATIONS

A. Jeffery Cline's Experience with the SynchroMed II Device

6. Plaintiff is a 59 year old male with a history of failed back syndrome, neuritis or radiculitis due to a ruptured disc in his spine, degenerative arthritis of the spine with narrowing of the spinal canal and compression of spinal cord nerves, and chronic back and lower extremity pain.

7. On or about October 18, 2006, Mr. Cline first had a SynchroMed II Device implanted, comprised of a model no. 8630-20 SynchroMed II Device (hereinafter the "Device") and an intrathecal catheter system (hereinafter the "first catheter"), which was used to deliver pain medication including Bupivacaine, Hydromorphone, and/or other opiate pain medications.

8. At some point during the use of his first pump and first catheter, the tip of the first catheter broke off and lodged within Mr. Cline's spinal canal.

9. On or about June 28, 2013, due to this defect with the first catheter and the expired lifecycle of the first pump, Mr. Cline had his first pump and first catheter (including the fractured catheter tip) removed and replaced with a second SynchroMed II Device, comprised of a model no. 8637-20 pump, serial no. NGP387637H (hereinafter the "second pump") and a model 8709SC catheter (hereinafter the "second catheter").

10. On or about August 6, 2013, Mr. Cline began to receive care at Ohio State University Wexner Medical Center (OSU) 410 W 10th Ave, Columbus, Ohio 43210.

11. On or about February 20, 2017, Mr. Cline began to notice an increase in his pain levels and discomfort with his device after a change in medication from Hydromorphone to Hydromorphone with Bupivacaine.

12. On or about April 24, 2017, Mr. Cline received a refill in his device. Dr. Steven A. Severyn, MD noted in the procedure note that “a small amount of air in the form of extension tubing bubbles was observed to be removed.” The doctor aspirated liquid to remove the bubbles prior to re-clamping the extension tubing.

13. On or about July 26, 2017, Mr. Cline contacted OSU stating that Mr. Cline believed his pump may be broken or stalled or shut off. Mr. Cline also stated that he was scared and in pain. When a registered nurse returned his call, Mr. Cline stated his back pain was so severe he couldn’t stand it. He believed, at that time, that his catheter was smashed or not working and wanted the device tested for functionality.

14. On or about July 28, 2017, Dr. Severyn ordered a catheter dye study due to severe pain and concern that the catheter may not be functioning correctly.

15. As of September 11, 2017, records indicate that Mr. Cline had resorted to taking oral medications, including Methadone and Oxycodone, to control the pain in his spine and legs. On or about this date, records also indicate that Dr. Severyn planned to perform a catheter dye study in four weeks because the second catheter could not be deemed perfectly functional and may need to be replaced.

16. On or about January 18, 2018, Mr. Cline received an MRI at the Comprehensive Spine Center, OSU Carepoint East, 543 Taylor Ave., Columbus, Ohio 43203, by Dr. John Vetter.

This study was conducted due to increasing pain in his left lower extremity as well as numbness and tingling and weakness which had worsened over the past year. Dr. Vetter noted that Mr. Cline exhibited chronic pain behaviors. The study was abnormal showing chronic left L5 radiculopathy.

17. In or about May 2018, Mr. Cline received an MRI at a separate facility with dye contrast which was then sent to OSU.

18. On or about June 19, 2018, nurse practitioner Christina D. McGhee noted that she reviewed the report of Mr. Cline's MRI and believed there was a possible arachnoid cyst spanning the L1-3 space of his spine. This is the same location where Mr. Cline's catheter was noted to have been on September 22, 2016, the date of Mr. Cline's previous MRI. Ms. McGhee noted that a catheter dye study had been ordered on May 7, 2018 and set for July 15, 2018.

19. On or about June 26, 2018, Ms. McGhee noted that she, and Mr. Cline's other doctors, suspected a granuloma had formed in the space along the L1-3 of Mr. Cline's spine.

20. On or about July 31, 2018, Mr. Cline was seen at OSU regarding the granuloma which formed around the area of his second catheter and for extreme lower back and lower extremity pain. At this time, Ms. McGhee notes that, in addition to Mr. Cline's intrathecal dose of opiate medication, he has also required the use of oral Methadone and Percocet through his PCP to help manage his pain. At this time, it is notated that Mr. Cline was seen to "continue with his pump taper" whereby doctors intended to slowly replace the hydromorphone and bupivacaine solution with saline over time and, after six months, re image the lumbar spine to check on the granuloma.

21. At the present time Mr. Cline still has his SynchroMed II Device implanted and is still suffering from a granuloma in the area of his spine where the second catheter is located.

22. As a result of the aforementioned defects and malfunctions, Plaintiff's SynchroMed II Device failed to deliver the prescribed medication as programmed, resulting in underdosing and withdrawal from opiate medications as well as severe pain and failure to properly manage his pain. Additionally, due to defects in the second catheter and/or pump-catheter connector, Mr. Cline has suffered a granuloma in the area of his spine where the catheter meets with the spinal cavity.

23. As a result of the Device failure, Mr. Cline faces lasting physical and mental injury. Due to his SynchroMed II Device failure and resulting injuries, Mr. Cline's social, emotional, and physical health have been compromised.

24. As a foreseeable, direct, and proximate result of Medtronic's conduct described herein, Jeffery Cline has suffered damages, including pain and suffering, lasting injury, mental anxiety and anguish, and medical bills in amounts to be proven at trial.

B. Background of the SynchroMed II Device

25. The SynchroMed II Device is a programmable drug infusion system implanted in the body for drug delivery. The SynchroMed II Device includes an infusion pump connected to a thin, flexible catheter attached to the intrathecal space (spinal canal) of the patient, into which the pump delivers medication.

26. The entire SynchroMed II Device is implanted and remains under the skin. A clinician measures a precise amount of medication and injects the medication into the pump's reservoir fill port. The medication passes through a reservoir valve and into the pump reservoir. At normal body temperatures, pressurized gas, used as a propellant, is stored below the reservoir and it expands and exerts constant pressure on the reservoir. This pressure pushes the medication into the pump tubing. The battery-powered electronics and motor gears deliver a programmed

dose of medication through the tubing out through a catheter port and into a catheter. Medication delivery then continues through the catheter tubing and into the intrathecal space of a patient.

27. The intrathecal catheters and sutureless revision kits of the SynchroMed II Device are designed to connect the pump with the patient's intrathecal space. Each catheter has a pre-attached strain relief sleeve, a connector pin, and a sutureless pump connector (also known as a revision kit) that connects to the SynchroMed II pump.

28. The SynchroMed II Device is a Class III medical device, approved by the U.S. Food and Drug Administration (FDA) through the Premarket Approval (PMA) process on March 14, 1988, PMA No. P860004.

29. Since the initial approval, Medtronic has sought FDA approval of at least 351 supplements or changes to the originally approved Device.

30. The pump of the SynchroMed II Device is supplied in 20- and 40-ml reservoir sizes, model nos. 8637-20 and 8637-40, respectively.

31. According to Medtronic's SynchroMed II "System Components Sheet," as well as information identified through the FDA's recall database, the catheter of the SynchroMed II Device is supplied as one of the following brands and models, which are connected to the pump using the following revision kit models:

<i>Brand</i>	<i>Catheter Model No.</i>	<i>Connector / Revision Kit Model No.</i>
Indura	8709	8575, 8578
Indura	8709SC	8578
Indura	8711	Not specified
Not Specified	8731	8596, 8596SC, 8598, 8598A
Not Specified	8731SC	8596SC, 8598A
Ascenda	8780	8784
Ascenda	8781	8784

32. According to Medtronic's SynchroMed II "Indications, Drug Stability, and Emergency Procedures Reference Manual," the SynchroMed II Device is FDA-approved solely for the following uses:

a. The chronic intrathecal infusion of Infumorph (preservative-free morphine sulfate sterile solution) in the treatment of chronic intractable pain, with a maximum approved concentration of 25 mg/ml.

b. The chronic intrathecal infusion of Prialt (preservative-free ziconotide sterile solution) for the management of severe chronic pain, with a maximum approved concentration of 100 µg/ml.

c. The chronic intrathecal infusion of Lioresal Intrathecal (baclofen injection) in the management of severe spasticity, with a maximum approved concentration of 2 mg/ml.

1. Legal Requirements Following Premarket Approval of the SynchroMed II Device.

33. Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III medical devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, these devices require a premarket approval (PMA) application under Section 515 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) before they can be sold in the United States. The SynchroMed II Device is a Class III medical device.

34. In a PMA application, the applicant is required to supply information to the FDA. The information required includes device description, clinical safety trials, methods of its product

testing, design of the device and specific manufacturing controls, outcome evaluation, and proposed labeling. The FDA does not conduct independent testing on a medical device in a PMA application. The FDA reviews the documentation provided to them by the PMA applicant and relies on the veracity of the company. The PMA applicant is solely responsible for submitting all truthful and necessary documentation to the FDA.

35. Once an application for PMA is approved, the holder (here, Medtronic) must comply with any and all post-approval requirements established by statute, the FDA, and federal regulations.

36. In particular, federal regulations require a PMA holder such as Medtronic to comply with the following requirements:

a. Adverse Events. Review, evaluate, and report to the FDA adverse events associated with the medical device.

i. Report individual adverse events within 30 days after becoming aware of an adverse event or aware of a reportable death, serious injury or malfunction, 21 C.F.R. § 803.10(c)(1); and

ii. Report individual adverse events no later than five work days after becoming aware of a “reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health,” 21 C.F.R. § 803.10(c)(2)(i).

b. Quality System. Establish and maintain a quality system that is appropriate for the specific medical devices designed or manufactured and that meets the requirement of this part. 21 C.F.R. § 820.5.

c. Management Responsibility. Management with executive responsibility shall establish its policy and objectives for, and commitment to quality. 21 C.F.R. § 820.20.

d. Qualified Personnel. Have sufficient personnel with the necessary educational background, training, and experience to assure that all activities required by this part are correctly performed. 21 C.F.R. § 820.25.

e. Corrective and Preventative Action (CAPA). Establish and maintain procedures for implementing corrective and preventive action, and document all CAPA activities. 21 C.F.R. § 820.100.

f. Complaint Files. Maintain complaint files, processed in a uniform and timely manner, oral complaints must be documents and must be evaluated to determine whether the complaint represents a reportable event under Medical Device Reporting. 21 C.F.R. § 820.198.

g. Statistical Techniques. Establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling and verifying the acceptability of process capability and product characteristics. 21 C.F.R. § 820.250.

h. Misbranded Drugs and Devices Prohibited. A device shall be deemed to be “misbranded” if, among other things, there has been a failure or refusal to give required notification or to furnish required material or information to the FDA. 21 U.S.C. § 352(t).

i. Adulterated Products Prohibited. If the manufacturer fails to ensure that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with applicable requirements, including but not limited to the Current Good Manufacturing Practice (CGMP) requirement of the Quality System

regulations found at Title 21 Code of Federal Regulations Section 820, then such products are considered “adulterated.” 21 U.S.C. § 351(h).

j. Off-Label Promotion Prohibited. A product may not be manufactured packaged, stored, labeled, distributed, advertised, or promoted in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device. 21 C.F.R. § 814.80.

2. Overview of FDA Inspections and Defendants’ Violations

37. To ensure compliance with these statutes and regulations, the FDA conducts inspections of medical device manufacturing and quality-control facilities. Following such inspections, FDA inspectors issue FDA Form 483 documents, also known as Inspectional Observations, which list conditions or practices that indicate potential violations of statutes or regulations. The FDA may also issue a formal Warning Letter if, upon further review of the Inspectional Observations, the FDA determines that serious statutory or regulatory violations exist at a medical device manufacturing or quality-control facility.

38. Medtronic, in their manufacture of the SynchroMed II Device (including not only the pump but also catheters), violated federal law governing manufacture and quality control of PMA medical devices, which was discovered during a series of inspections by the FDA at Medtronic’s manufacturing and quality control plants in Minneapolis, Minnesota and Juncos, Puerto Rico.

39. The inspections were followed by a series of Warning Letters to Medtronic that identify federal manufacturing and quality control violations at the plants that ultimately led to an April 27, 2015 Complaint Requesting a Permanent Injunction filed against Medtronic by the U.S. Department of Justice and U.S. Department of Health and Human Services, and a Court- Ordered

Consent Decree imposing a moratorium on the manufacture, sale, and distribution of the SynchroMed II Device in violation of federal law.

40. In addition, since receiving PMA approval, the SynchroMed II Device and its components associated with PMA No. P860004 have been subject to no fewer than 72 recalls.

41. These Warning Letters, recalls, and injunction, which include specific references to the SynchroMed II pump as well as its affiliated intrathecal catheters, speak to the seriousness of Defendants' violations of federal law and negligence in the manufacture of the SynchroMed II Device.

3. FDA Inspections and Warning Letters

42. In 2006, 2007, 2008, 2009, 2012, and 2013, during the time Plaintiff's SynchroMed II Devices were being manufactured by Medtronic, the FDA conducted numerous inspections of Medtronic's manufacturing and quality-control facilities in Minneapolis, Minnesota and Juncos, Puerto Rico, discovering a multitude of significant violations of federal law governing the manufacture and quality control of PMA medical devices including the SynchroMed II Device and associated intrathecal catheters, as recorded in FDA Form 483s and Warning Letters issued to Medtronic.

2006 Inspection and 2006 Warning Letter.¹

43. From May 18 to June 22, 2006, the FDA conducted an inspection of Medtronic's manufacturing plant located at 800 53rd Avenue NE, Minneapolis, Minnesota 55421, where Medtronic "manufacturers manufactures implantable drug infusion . . . products to treat pain [and] movement disorders."

¹ See Ex. 1, FDA Warning Letter (Aug. 29, 2006). All quotations in the subparagraphs of this paragraph are sourced from this 2006 Warning Letter.

44. On August 29, 2006, the FDA issued Medtronic a Warning Letter concerning this inspection.

45. This inspection revealed that the SynchroMed II Device was “adulterated under Section 501(h) of the Act [21 U.S.C. 351(h)], in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, found at Title 21, Code of Federal Regulations (CFR), Part 820.”

46. The 2006 Warning Letter enumerated the following “significant deviations” from the CGMP regulations with respect to catheters and pumps:

a. Violation of 21 C.F.R. § 820.30(c): Failure to implement procedures to ensure that a device’s design input requirements are appropriate and address its intended use, including user/patient needs, in that design input work for intrathecal catheters had not resulted in development of a complete design specification for the catheter tip bond.;

b. Violation of 21 C.F.R. § 820.30(g): Failure to conduct design validation using production units or their equivalents, in that design validation testing of intrathecal catheters was conducted with catheters manufactured with a tip marker bonding process that was different than that used in production;

c. Violation of 21 C.F.R. § 820.75(a): Failure to validate a process whose results cannot be fully verified by subsequent inspections and tests, in that the bonding process for the catheter has not been validated;

d. Violation of 21 C.F.R. § 820.70(a): Failure to control production processes to ensure that a device conforms to its specification, in that the bonding manufacturing procedures contained nonconforming instructions.

e. Violation of 21 C.F.R. § 820.100(a)(2): Failure to implement CAPA procedures addressing the investigation of the cause of nonconformities, including closing CAPAs without proper root cause analyses, with incorrect conclusions, or without evidence to support conclusions.

f. Violation of 21 C.F.R. § 820.100(a)(5): Failure to implement changes in methods and procedures needed to correct and prevent identified quality problems, in that although a CAPA called for a catheter tip redesign, product specification was not changed, the revised manufacturing process was not validated, and no process monitoring was conducted.

g. Violation of 21 C.F.R. § 820.100(a)(3): Failure to identify all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems; and

h. Violation of 21 C.F.R. § 820.184: Failure to implement procedures to ensure that device history records for each batch, or unit are maintained to demonstrate that the device is manufactured in accordance with regulations.

47. The Warning Letter concluded that these violations “may be symptomatic of serious underlying problems in your firm’s manufacturing quality assurance systems” and called for a follow-up inspection.

2006–07 Inspection and 2007 Warning Letter.²

48. From November 21, 2006 to January 24, 2007, the FDA conducted a follow-up inspection of Medtronic’s manufacturing plant located at 800 53rd Avenue NE, Minneapolis, Minnesota 55421, where Medtronic “manufacturers implantable drug infusion . . . products.”

49. On July 3, 2007, the FDA issued Medtronic a Warning Letter concerning this inspection.

50. This inspection revealed that the SynchroMed II Device was “adulterated within the meaning of section 501(h) of the Act [21 U.S.C. § 351(h)], in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations, (21 CFR) Part 820.”

51. Specifically with respect to adulteration, the FDA found that Medtronic violated 21 C.F.R. § 820.198(a)(3) through its “[f]ailure to implement complaint handling procedures to ensure that all complaints are evaluated to determine whether the complaint represents an event that must be filed as a Medical Device Report under 21 CFR Part 803.”

52. This inspection also revealed that the SynchroMed II Device was “misbranded under section 502(t)(2) of the Act [21 U.S.C. § 352(t)(2)], in that [Medtronic] failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act (21 U.S.C. § 360i), and 21 CFR Part 803—Medical Device Reporting (MDR) regulation.”

53. Specifically with respect to this misbranding, the FDA found that Medtronic violated 21 C.F.R. § 803.50(a)(1) through its “[f]ailure to submit MDR reports within 30 days of

² See Ex. 2, FDA Warning Letter (July 3, 2007). All quotations in the subparagraphs of this paragraph are sourced from this 2007 Warning Letter. See also Ex. 3, FDA Form 483 (Jan. 24, 2007).

receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.” Medtronic:

- a. failed to report SynchroMed II Device’s intrathecal catheters associated with granuloma or inflammatory masses at or near the distal tip, which the FDA considers “serious injuries”;
- b. failed to report SynchroMed II Device’s intrathecal catheter fractures;
- c. failed to report a malfunction MDR, required when a marketed device malfunction would likely cause or contribute to a reportable death or serious injury;
- d. failed to submit MDR reports within 30 days of learning of a problem (pump malfunctions, catheter fracture or separation, inflammatory masses and granulomas) with the SynchroMed II device in the medical literature; and
- e. failed to report consumer self-reported adverse events.

54. The inspection further revealed that the SynchroMed II Device was also “misbranded under section 502(t)(2) of the Act [21 U.S.C. § 352(t)(2)], in that [Medtronic] failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 806—Reports of Corrections and Removals.”

55. Specifically with respect to this additional misbranding, the FDA found that Medtronic violated 21 C.F.R. § 806.10(a)(1) because a “correction or removal conducted to reduce a risk to health posed by a device was not reported in writing to FDA” concerning the risk of an inflammatory mass occluding intrathecal catheters.

56. The 2007 Warning Letter further warned Medtronic: “[Y]our firm has several procedures for Medical Device Reporting and Adverse Drug Experience Reporting. These

procedures, in turn reference several other procedures. Your firm's current problems regarding MDR reporting, as discussed above in this Warning Letter, may be exacerbated by the complexity of your procedures and might have contributed to your firm's deviations from the regulations regarding MDR reporting."

57. The 2007 Warning Letter concluded by also revealing several ongoing violations at Medtronic's Minneapolis Plant's Quality System that were noted in a Form 483, stating "[t]he specific violations noted in this letter and Form FDA 483 may be symptomatic of serious underlying problems in your firm's manufacturing and Quality Assurance systems." Specifically, the FDA warned that Medtronic failed to achieve consistent compliance in areas such as design controls in violation of 21 C.F.R. § 820.30 and failed to achieve consistent CAPA compliance in violation of 21 C.F.R. § 820.100.

2008 Inspection and 2009 Warning Letter.³

58. From November 12 to December 15, 2008, the FDA conducted an inspection of Medtronic's manufacturing plant located at Road 31, Km 24, Ceiba Norte Industrial Park, Juncos, Puerto Rico, where Medtronic "manufacturers SynchroMed II Pumps."

59. On June 1, 2009, the FDA issued Medtronic a Warning Letter concerning this inspection.

60. This inspection "revealed that the SynchroMed II Pumps are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. §351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820."

³ See Ex. 4, FDA Warning Letter (June 1, 2009). All quotations in the subparagraphs of this paragraph are sourced from this 2009 Warning Letter. See also Ex. 5, FDA Form 483 (Dec. 15, 2008).

61. The FDA enumerated the following violations in the 2009 Warning Letter:

a. Violation of 21 C.F.R. § 820.70(a): “Failure to establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications, which shall include monitoring and control of process parameters and component and device characteristics during production,” in that pumps were manufactured without propellant; “did not show evidence of a perforated septum,” which is “performed to detect obstruction . . . early in the manufacturing process”; and lacked “a safety mechanism that serves to ensure that the pump is never overfilled.”

b. Violation of 21 C.F.R. § 820.100(a): “Failure to establish and maintain procedures for implementing corrective and preventive action that include identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems,” in that a critical step was left out of the pump manufacturing process concerning “critical internal functions such as calculating drug reservoir levels and drug dispensing rates.” Despite numerous complaints that Medtronic received regarding accuracy rates, Medtronic failed to conduct any type of investigation into this problem.

c. Violation of 21 C.F.R. § 820.184: “Failure to establish and maintain procedures to ensure that Device History Records (DHR’s) for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the Device Master Record (DMR),” in that pump sterilization processes were not performed in the order specified by Medtronic procedures; and

d. Violation of 21 C.F.R. § 820.198(c): “Failure to review, evaluate, and investigate complaints involving the possible failure of a device, labeling, or packaging to meet any of its specifications,” in that, for several complaints of infections from nonsterile

pumps, “a copy of [Medtronic’s] investigation was not included as part of the complaint record, there was no reference to a specific investigation report number, . . . there was no documentation whether the investigation was successfully closed, . . . [and] there was no record in the complaint file that Medical Device Reports were filed by [Medtronic] with FDA.”

62. The Warning Letter concluded that these violations “may be symptomatic of serious problems in your firm’s manufacturing quality assurance systems.”

2012 Investigation and 2012 Warning Letter.⁴

63. From March 14 to May 9, 2012, the FDA conducted an inspection of Medtronic’s manufacturing plant located at 7000 Central Avenue NE, Minneapolis, Minnesota 55432, where Medtronic “manufactures implantable drug infusion systems.”

64. On July 17, 2012, the FDA issued Medtronic a Warning Letter concerning this inspection.

65. This inspection revealed that Medtronic’s SynchroMed II Devices were “adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (21 CFR), Part 820.”

66. The FDA enumerated the following violations in the 2012 Warning Letter:

a. Violation of 21 C.F.R. § 820.100(a): “Failure to establish adequate procedures for corrective and preventive action,” in that Medtronic failed to identify “the

⁴ See Ex. 6, FDA Warning Letter (July 17, 2012). All quotations in the subparagraphs of this paragraph are sourced from this 2012 Warning Letter.

actions to correct and prevent recurrence of nonconforming product,” specifically motor stalls due to corrosion. Specifically, Medtronic did not address “GCAPA 1485, opened October 26, 2007, [which] relates to motor corrosion resulting in device field failure (motor stall). Within the Investigation Report for SynchroMed II Pump Corrosion (NDHF1119-88863), it states ‘corrosion [...] can result in partial or complete removal of gear teeth.’ This can ‘seize’ the motor altogether or ‘gear wheel [...] will continue to rotate, but there may be no drug delivery in the region of missing teeth.’ . . . This GCAPA includes 567 complaints and has not been closed.”;

b. Violation of 21 C.F.R. § 820.198(a): “Failure to establish adequate procedures for receiving, reviewing, and evaluating complaints by a formally designated unit,” in that “[c]omplaint information received during a call was not documented”; and

c. Violation of 21 C.F.R. § 820.198(c): “Failure to review, evaluate and investigate, where necessary, complaints involving the possible failure of a device to meet any of its specifications,” in that “Product Performance Specialists did not adequately evaluate complaints,” “[c]oding of similar complaints is inconsistent,” and “[t]rending of complaint data / coding for evaluation was not completed per procedures.”

67. The FDA expressed its significant “concern[] that incomplete complaint data and incorrect coding decisions . . . may have compromised Medtronic’s ability to detect and investigate [safety] signals,” i.e., signs of safety problems.

68. The Warning Letter concluded that these violations “may be symptomatic of serious problems in your firm’s manufacturing and quality assurance systems.”

2013 Inspection.⁵

69. From February 14 to April 3, 2013, the FDA conducted another inspection of Medtronic's manufacturing plant located at 7000 Central Avenue NE, Minneapolis, Minnesota 55432.

70. On April 3, 2013, the FDA issued a Form 483 informing Medtronic that that the plant failed to manufacture devices that adequately conform to specifications and instead manufactured devices that are not adequately controlled. Specifically, Medtronic:

a. distributed nonconforming intrathecal catheters that were prone to occlusion and

b. failed to establish adequate CAPA procedures, in that "[a]ctions needed to correct and prevent recurrence of a quality problem were identified but not implemented" concerning electrical shorting leading to pump motor stalls and implementation of recommendations from the Risk Evaluation Board, "Health Hazard Assessments for high priority CAPAs with the highest patient severity of death were not completed in a timely fashion," and "Health Hazard Assessments have not been updated after CAPA effectiveness monitoring signaled an increase in the rate of occurrence" of hazards involving intrathecal catheter occlusion.

71. Throughout the history of the manufacture of the SynchroMed II Device, the FDA has repeatedly notified Medtronic that their manufacture of the SynchroMed II Device failed to conform to manufacturing requirements enumerated in federal regulations and statutes. These federal violations caused the aforementioned defects and malfunctions in Plaintiff's SynchroMed II pump and catheter, which caused his injuries and damages alleged herein.

⁵ See Ex. 7, FDA Form 483 (Apr. 3, 2013).

4. Recalls of the SynchroMed II Pump and Catheters.

72. A recall is an action taken to address a problem with a medical device that violates federal law.

73. Recalls are classified as either Class I, Class II, or Class III. A Class I recall is issued for a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. A Class II recall is issued for a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. Finally, a Class III recall is issued for a situation in which use of or exposure to a violative product is less likely to cause adverse health consequences.

74. The FDA has issued at least 19 Class I and II recalls specifically for SynchroMed II pump models during the time the SynchroMed II Device has been on the market, as summarized in the following table:

<i>Recall No.</i>	<i>Class</i>	<i>Pump Model No.</i>	<i>Recall Reason</i>
Z-1040-04	2	8637-20 & 8637-40	Mislabeling of pump reservoir size, resulting in overfilling and overinfusion
Z-2181-2008	2	8637-20	Pumps manufactured without propellant, resulting in cessation of therapy, underinfusion, and withdrawal
Z-2182-2008	2	8637-40	Pumps manufactured without propellant, resulting in cessation of therapy, underinfusion, and withdrawal
Z-0591-2009	2	8637-20	MRI-related motor stall, resulting in cessation of therapy, underinfusion, and withdrawal
Z-0592-2009	2	8637-40	MRI-related motor stall, resulting in cessation of therapy, underinfusion, and withdrawal
Z-2276-2009	2	8637-20 & 8637-40	Battery failure, resulting in cessation of therapy, underinfusion, and withdrawal

<i>Recall No.</i>	<i>Class</i>	<i>Pump Model No.</i>	<i>Recall Reason</i>
Z-1060-2011	1	8637-20 & 8637-40	Inadequate instruction for filling/refilling of pumps, resulting in injection of some or all of the prescribed drug into the patient's subcutaneous issue (an inadvertent "pocket fill") and corresponding overinfusion
Z-1061-2011	1	8637-20 & 8637-40	Inadequate instruction for filling/refilling of pumps, resulting in injection of some or all of the prescribed drug into the patient's subcutaneous issue (an inadvertent "pocket fill") and corresponding overinfusion
Z-3043-2011	1	8637-20 & 8637-40	Battery failure, resulting in cessation of therapy, underinfusion, and withdrawal
Z-1338-2012	2	8637-20 & 8637-40	Software failure resulting in incorrect display of the scheduled pump replacement date
Z-0497-2013	1	8637-20 & 8637-40	Use of unapproved drugs in the pumps and corresponding motor stall, resulting in cessation of therapy, underinfusion, and withdrawal
Z-1570-2013	1	8637-20 & 8637-40	Unintended delivery of drugs during the priming bolus procedure, resulting in life-threatening overdose and subsequent withdrawal
Z-1579-2013	1	8637-20 & 8637-40	Internal electrical shorting, resulting in a motor stall or battery failure, cessation of therapy, underinfusion, and withdrawal
Z-1570-2014	2	8637-20 & 8637-40	Overinfusion, resulting in life-threatening overdose and corresponding drug withdrawal
Z-1681-2015	2	8637-20 & 8637-40	Alarm failure, resulting in cessation of therapy, underinfusion, and withdrawal due to lack of audible warning of low or empty drug reservoir, pump end-of-service, pump motor stall, pump stoppage, or critical memory error
Z-0788-2017	1	8637-20 & 8637-40	Unintended delivery of drugs during the priming bolus procedure, resulting in life-threatening overdose and subsequent withdrawal
Z-1694-2017	2	8637-40	Software error preventing pump interrogation, resulting in cessation of therapy, underinfusion, and withdrawal due to inability to update or refill the pump

<i>Recall No.</i>	<i>Class</i>	<i>Pump Model No.</i>	<i>Recall Reason</i>
Z-0896-2018	2	8637-20 & 8637-40	Permanent motor stall due to corrosive wear, resulting in cessation of therapy, underinfusion, and withdrawal
Z-0508-2020	1	8637-20 & 8637-40	Permanent motor stall due to presence of a foreign particle inside the pump motor assembly, resulting in cessation of therapy, underinfusion, and withdrawal

75. The FDA has also issued at least 27 recalls specifically concerning SynchroMed II catheters and catheter-pump connectors during the time the SynchroMed II Device has been on the market, as summarized in the following table:

<i>Recall No.</i>	<i>Class</i>	<i>Product</i>	<i>Model No. (Brand)</i>	<i>Recall Reason</i>
Z-1414-06	1	Catheter	8731	Tip dislodgement during implantation
Z-1415-06	1	Connector	8598	Tip dislodgement during implantation
Z-1308-2008	2	Connector	8596SC	Packaging of the incorrect pin to connect the catheter to the pump
Z-1150-2008	1	Catheter	All catheters used with SynchroMed II Pump model no. 8637-20	Formation of inflammatory masses near the tip of intrathecal catheters
Z-1151-2008	1	Catheter	All catheters used with SynchroMed II Pump model no. 8637-40	Formation of inflammatory masses near the tip of intrathecal catheters
Z-2171-2008	2	Connector	8578	Inability to completely connect catheter to pump, resulting in leakage or disconnection of the catheter
Z-2172-2008	2	Connector	8596SC	Inability to completely connect catheter to pump, resulting in leakage or disconnection of the catheter
Z-2173-2008	2	Catheter	8709SC (Indura)	Inability to completely connect catheter to pump, resulting in leakage or disconnection of the catheter

<i>Recall No.</i>	<i>Class</i>	<i>Product</i>	<i>Model No. (Brand)</i>	<i>Recall Reason</i>
Z-2174-2008	2	Catheter	8731SC	Inability to completely connect catheter to pump, resulting in leakage or disconnection of the catheter
Z-2380-2008	1	Catheter	8709SC (Indura)	Disconnection of catheters from the pump, or occlusion between the sutureless pump connector and the catheter port on the pump.
Z-2381-2008	1	Catheter	8731SC	Disconnection of catheters from the pump, or occlusion between the sutureless pump connector and the catheter port on the pump.
Z-2382-2008	1	Connector	8578	Disconnection of catheters from the pump, or occlusion between the sutureless pump connector and the catheter port on the pump.
Z-2383-2008	1	Connector	8596SC	Disconnection of catheters from the pump, or occlusion between the sutureless pump connector and the catheter port on the pump.
Z-2073-2009	1	Catheter	8709SC (Indura)	Labeling error incorrectly stating catheter-pump compatibility
Z-2074-2009	1	Catheter	8731SC	Labeling error incorrectly stating catheter-pump compatibility
Z-2075-2009	1	Connector	8596SC	Labeling error incorrectly stating catheter-pump compatibility
Z-2076-2009	1	Connector	8578	Labeling error incorrectly stating catheter-pump compatibility
Z-0334-2011	2	Catheter	8731SC	Presence of endotoxin in excess of United States Pharmacopeial Convention (USP) limits
Z-0335-2011	2	Connector	8598A	Presence of endotoxin in excess of United States Pharmacopeial Convention (USP) limits
Z-1573-2013	1	Connector	8578	Potential for catheter misalignment and occlusion at the catheter-to-pump interface.
Z-1574-2013	1	Connector	8596SC	Potential for catheter misalignment and occlusion at the catheter-to-pump interface.

<i>Recall No.</i>	<i>Class</i>	<i>Product</i>	<i>Model No. (Brand)</i>	<i>Recall Reason</i>
Z-1575-2013	1	Catheter	8709SC (Indura)	Potential for catheter misalignment and occlusion at the catheter-to-pump interface.
Z-1576-2013	1	Catheter	8731SC	Potential for catheter misalignment and occlusion at the catheter-to-pump interface.
Z-1723-2014	2	Catheter	8780 (Ascenda)	Presence of endotoxin in excess of USP limits
Z-2172-2014	2	Catheter / Connector	8780 & 8781 (Ascenda) / 8784	Catheter retainer ring failed specification criteria, resulting in possible disconnection of the catheter from the pump
Z-1271-2016	2	Catheter	8781 (Ascenda)	Incorrect package labeling and lack of all components necessary to complete the implant procedure
Z-0537-2018	3	Catheter / Connector	8780 & 8781 (Ascenda) / 8784	Increased potential for kinking where the catheter connects to the pump

5. Violations of the Permanent Injunction Resulting in the Manufacture, Distribution, and Sale of Plaintiff's Defective and Malfunctioning SynchroMed II Device.

76. Throughout the history of the manufacture of the SynchroMed II Device, Medtronic has shown an indifference to federal manufacturing requirements. Further, Medtronic, with full knowledge that it was manufacturing the SynchroMed II Device in violation of law, nonetheless demonstrated a pattern of delayed responses or complete failures to respond to reported and known safety issues with the SynchroMed II Device.

77. Because of Medtronic's years-long pattern of indifference to regulatory authority, noncompliance with federal manufacturing requirements, and violations of federal law, the U.S. Department of Justice and the U.S. Department of Health and Human Services on April 27, 2015

filed a Complaint against Medtronic requesting a Consent Decree for Permanent Injunction against the manufacture, distribution, and sale of the SynchroMed II Device.⁶

78. The Complaint alleges that Medtronic is “well aware that their practices violate the [FD&C] Act. FDA has repeatedly warned Defendants, both orally and in writing, about their violative conduct, and has emphasized the importance of Defendants’ compliance with the Act.”⁷

79. In addition to the cited Warning Letters, the Complaint alleges that representatives of Medtronic attended a meeting with FDA’s Center for Devices and Radiological Health and Minneapolis District Office on January 31, 2013. At this meeting, “Defendants stated that they were aware of the violations at their facilities and were taking steps to correct them.”⁸

80. The Complaint further alleges Medtronic made promises to correct their violations in written responses to each inspection; however, the Complaint alleged that none of the responses contained adequate evidence that Medtronic corrected their deviations.⁹

81. The United States Attorney stated in the Complaint that, “[b]ased upon Defendants’ conduct, Plaintiff believes that, unless restrained by order of this Court, Defendants will continue to violate 21 USC §§ 331(a) and (k)”—introducing into interstate commerce any article of device that is adulterated or misbranded, or causing any article of device to become adulterated or misbranded while such devices are held for sale after shipment in interstate commerce.¹⁰

82. The United States’ Complaint requested a permanent injunction to restrain Medtronic in their manufacture, distribution, and sale of the SynchroMed II Device from their continued violation of federal regulations, and specifically:

⁶ Ex. 15, Complaint for Permanent Injunction, *United States v. Medtronic, Inc.*, No. 15-cv-2168 (D. Minn. Apr. 27, 2015), ECF No. 1.

⁷ *Id.* ¶¶ 15–17.

⁸ *Id.* ¶ 18.

⁹ *Id.* ¶¶ 19–20.

¹⁰ *Id.* ¶ 21.

That the Court order Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, to cease directly and indirectly manufacturing, packing, labeling, and distributing (domestically and internationally) SynchroMed II implantable infusion pumps at or from its Medtronic's Neuromodulation facilities, unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold and distribute the SynchroMed II implantable infusion pumps are established, operated, and administered in compliance with 21 USC 360j(f)(1) and the Quality System regulation prescribed in 21 C.F.R. Part 820, and in a manner that has been found acceptable to FDA.¹¹

83. On April 27, 2015, United States District Court Judge Joan N. Erickson signed a Consent Decree of Permanent Injunction against Medtronic preventing the manufacture, distribution, and sale of Medtronic SynchroMed Implantable Infusion Pump systems in violation of the terms of the Consent Decree.¹²

84. Under the Consent Decree, Medtronic is “permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a), from directly or indirectly designing, manufacturing, processing, packing, labeling, holding, storing, and distributing, importing into or exporting from the United States of America, at or from any Medtronic Neuromodulation facilities, any model of, or components or accessories for, its SynchroMed devices.”¹³ Under the Consent Decree, the permanent injunction would be lifted only in the event that Medtronic complies with a series of enumerated requirements to ensure that it would cease violating federal law in the production of its SynchroMed II Device.¹⁴

¹¹ *Id.* at 8.

¹² Ex. 16, Consent Decree of Permanent Injunction, *United States v. Medtronic, Inc.*, No. 15-cv-2168 (D. Minn. Apr. 27, 2015), ECF No. 3.

¹³ *Id.* ¶ 6.

¹⁴ *Id.* ¶ 6.A.–J.

85. Under the Consent Decree, the permanent injunction would be lifted only in the event that Medtronic complies with a series of enumerated requirements to ensure that it would cease violating federal law in the production of its SynchroMed II Device.¹⁵

86. Although there is an exception to the permanent injunction in cases of medical necessity,¹⁶ Plaintiff's SynchroMed II Device was not medically necessary and/or did not satisfy the procedural requirements set forth in the Consent Decree for the medical-necessity exception to apply.

87. Medtronic continues to produce, distribute, and sell their SynchroMed II Device in violation of the Consent Decree.

C. Violations of Federal Law Resulting in Plaintiff's Defective and Malfunctioning SynchroMed II Device

88. The FDA repeatedly found SynchroMed II Devices were adulterated due to "significant deviations" from the CGMP regulations which the FDA felt were "symptomatic of serious underlying problems in [Medtronic's] quality assurance system."¹⁷ The same violation is repeated in the inspection and warning letters from 2006, 2007, 2009, and 2012, indicating an on-going issue with Medtronic's production of SynchroMed II Devices.¹⁸ Medtronic's continuous failure to comply with Federal law resulted in SynchroMed II Devices that did not meet PMA specifications, as further documented by associated recalls.

89. Highlighting those FDA actions which most support Plaintiff's factual allegations, Medtronic's specific violations of federal law which concern the manufacture of defective

¹⁵ *Id.* ¶ 6.A.–J.

¹⁶ *Id.* ¶ 9.A.

¹⁷ Ex. 1, FDA Warning Letter (Aug. 29, 2006); Ex. 2, FDA Warning Letter (July 3, 2007); Ex. 4, FDA Warning Letter (June 1, 2009); Ex. 6, FDA Warning Letter (July 17, 2012).

¹⁸ *Id.*

catheters are numerous. These include failure to perform design validation testing to ensure the manufacturing complied with PMA specifications (21 C.F.R. § 820.30(g)), failure to control production processes to ensure that device conformed to PMA specifications (21 C.F.R. § 820.70(a)), failure to address the cause of nonconformities (21 C.F.R. § 820.100(a)(2)), failure to correct and prevent the recurrence of nonconformities (21 C.F.R. § 820.100(a)(3)), and failure to address quality problems (21 C.F.R. § 820.100(a)(5)).¹⁹

90. The issues that existed during the 2006 inspections and warning letters were never addressed, leading to additional inspections and warning letters listing the same violations over, and over. The 2013 Inspection and Form 483, which was concluded only two months prior to Mr. Cline's implantation surgery, found Medtronic failed to manufacture devices that adequately conformed to PMA specifications, manufactured devices that were not adequately controlled, distributed nonconforming intrathecal catheters, and failed to establish adequate procedures to correct and prevent the recurrence of quality problems. Medtronic also violated 21 C.F.R. § 803.50(a)(1) by failing to report catheters associated with granulomas or fractures, and by failing to report consumer adverse events.

91. Medtronic's failures to report these device failures caused the catheters to be misbranded "misbranded under section 502(t)(2) of the Act [21 U.S.C. § 352(t)(2)], in that [Medtronic] failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i and 21 C.F.R. § 806.10(a)(1) because a "correction or removal conducted to reduce a risk to health posed by a device was not reported in writing to FDA" concerning the risk of an inflammatory mass occluding intrathecal catheters.²⁰

¹⁹ *Id.*

²⁰ *See* Ex. 1, FDA Warning Letter (Aug. 29, 2006).

92. The 2007 Warning Letter concluded by also revealing several ongoing violations at Medtronic's Minneapolis Plant's Quality System that were noted in a Form 483, stating "[t]he specific violations noted in this letter and Form FDA 483 may be symptomatic of serious underlying problems in your firm's manufacturing and Quality Assurance systems."²¹ Specifically, the FDA warned that Medtronic failed to achieve consistent compliance in areas such as design controls in violation of 21 C.F.R. § 820.30 and failed to achieve consistent CAPA compliance in violation of 21 C.F.R. § 820.100.²²

93. According to Medtronic's Urgent Medical Device Correction, issued in January of 2008, which was "intended to provide the medical community with the current post-market incidence of reported inflammatory mass," the associated "[i]nflammatory mass presents as a chronic inflammatory or granulomas mass at or near the distal tip of intrathecal catheters and has been reported with the intrathecal infusion of opioids."²³ Additionally, around 30% of patients with the granulomas reported a decrease in therapeutic effect and an increase in pain. Mr. Cline indisputably suffered this exact injury and these exact symptoms from his SynchroMed II, which was programmed to deliver opioid medication. Although issued five years prior to Mr. Cline's device implant, it clearly states in the letter that this same defect had been causing granulomas since at least 2001, indicating an ongoing problem which had, not only not been corrected, but had increased by five times the number of reported cases. The letter also states, verbatim, that "[t]he rate of occurrence of inflammatory mass is expected to continue to increase."

²¹ *Id.*

²² *Id.*

²³ Ex. 13, Medtronic, Urgent Medical Device Correction (2008). All quotations in the subparagraphs of this paragraph are sourced from this letter.

94. The associated Class I Recall, No. Z-1150-2008, was initiated on January 16, 2008, posted on March 22, 2008, and terminated on June 6, 2011.²⁴ The FDA issued this recall due to reports of inflammatory mass formations at or near the distal tip of intrathecal catheters which infuse opioids, baclofen, or chemotherapy drugs into patients. On information and belief, Plaintiff's Device was manufactured during the time period relevant to this recall and/or was subjected to the failures and violations necessitating this recall.

95. Plaintiff experienced the exact defect and injury addressed by this recall, as well as the 2006-07 inspection and following Warning Letter, Medtronic's own Urgent Medical Device Correction, and as referenced by Medtronic's series of violations and failures to correct its ongoing noncompliance with Federal law, CGMP regulations, and PMA specifications.

96. As a result, Plaintiff received a nonconforming catheter with the propensity to cause granulomas, occlude, leak, and otherwise fail to function properly causing years of overinfusion, underinfusion, failure of the device to properly deliver medication to the intrathecal space of his spine, and a granuloma due to defects in the second catheter or catheter tip implanted in that area.

V. CAUSES OF ACTION

COUNT I: Strict Liability Manufacturing Defect (R.C. § 2307.74)

97. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

98. Under Ohio law, "[a] product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards. A product

²⁴ Ex. 14, FDA Recall No. Z-1150-2008.

may be defective in manufacture or construction as described in this section even though its manufacturer exercised all possible care in its manufacture or construction.” Ohio Rev. Stat. § 2307.74.

99. The SynchroMed II Device is a Class III medical device, approved by the U.S. Food and Drug Administration (FDA) through the Premarket Approval (PMA) process on March 14, 1988, PMA No. P860004. This means that design specifications, formula, and performance standards are controlled by Federal regulation, including CGMPs, and the device’s PMA.

100. The SynchroMed II Device implanted in Plaintiff’s spine was manufactured in violation of the Federal Food, Drug, and Cosmetic Act and federal regulations promulgated pursuant thereto, and was manufactured in violation of CGMP requirements and Ohio law that parallels federal requirements.

101. The SynchroMed II Device implanted in Plaintiff was manufactured in deviation from the manufacturing specifications found in 21 C.F.R. Part 820. This deviations violate Ohio Rev. Stat. 3715.52. The quality-control requirements of the CGMPs are designed to ensure Medtronic’s products conform to manufacturing specifications, that non-conforming products do not reach the market, and that problems with products in the field are properly monitored, tracked and reported. The CGMPs require Medtronic to evaluate signals of unexpected or serious events of injury in the field and report to the FDA when a device causes, or is suspected to cause, injury in the field. A device that has been manufactured, monitored, packed, stored, inspected, or installed in violation of this requirement is deemed to be adulterated under 21 U.S.C. § 351(h).

102. As a result of numerous FDA inspections from 2006 through 2013 of Medtronic’s manufacturing plants in Minneapolis, Minnesota and Juncos, Puerto Rico, as alleged herein, the FDA determined that Medtronic violated specific CGMPs as previously pled including:

a. failure to achieve consistent compliance in areas such as design controls and to perform design validation testing to ensure the manufacturing complied with PMA specifications (21 C.F.R. § 820.30(g));

b. failure to control production processes to ensure that device conformed to PMA specifications (21 C.F.R. § 820.70(a));

c. failure to achieve consistent CAPA compliance (21 C.F.R. § 820.100);

d. failure to address the cause of nonconformities (21 C.F.R. § 820.100(a)(2));

e. failure to correct and prevent the recurrence of nonconformities (21 C.F.R. § 820.100(a)(3));

f. failing to report catheters associated with granulomas or fractures, and by failing to report consumer adverse events (21 C.F.R. § 803.50(a)(1));

g. failure or refusal to furnish material or information respecting the device that is required by law (21 U.S.C. § 360i and 21 C.F.R. § 806.10(a)(1)); and

h. failure to address quality problems (21 C.F.R. § 820.100(a)(5)) in that “correction or removal conducted to reduce a risk to health posed by a device was not reported in writing to FDA” concerning the risk of an inflammatory mass occluding intrathecal catheters and revealed several ongoing violations symptomatic of serious underlying problems in Medtronic’s manufacturing and Quality Assurance systems.

i. This is further supported by the 2007 Warning Letter, followed by recall no. Z-1150-2008, which found that Medtronic violated 21 C.F.R. § 806.10(a)(1) because a “correction or removal conducted to reduce a risk to health posed by a device was not reported in writing to FDA” concerning the risk of an inflammatory mass occluding intrathecal catheters and revealed several ongoing

violations symptomatic of serious underlying problems in Medtronic's manufacturing and Quality Assurance systems.

103. According to Mr. Cline's medical records, the SynchroMed II second catheter implanted into his body was defective in that it caused the formation of a granuloma around the area where the second catheter was placed and failed to properly deliver medication into his intrathecal space due to separation, occlusion, breakage, or other physical defect. The specifications of the SynchroMed II system indicate that it is intended, by the manufacturer, to deliver medication into the intrathecal space of the spine for the purposes of pain management. Mr. Cline's device was defective because it failed to perform this function, deviating from the specifications of the products design, formula, and/or performance standards in comparison to other SynchroMed II devices.

104. Medtronic did not exercise care to avoid the manufacture and sale of Mr. Cline's defective device, as shown by the numerous violations of Federal law listed above. Additionally, Medtronic did not exercise care to avoid the manufacture and sale of Mr. Cline's device as adulterated and misbranded under Federal law.

105. Under Ohio Rev. Stat. § 3715.52, "[t]he following acts and causing them are prohibited: The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded; The adulteration or misbranding of any food, drug, device, or cosmetic; The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise."

106. This parallels federal law which states that a manufacturer is prohibited from introducing, delivering, or selling an adulterated device into interstate commerce under 21 U.S.C. § 331(a)–(c), (k).

107. The SynchroMed II Device is a Class III medical device, approved by the U.S. Food and Drug Administration (FDA) through the Premarket Approval (PMA) process on March 14, 1988, PMA No. P860004. This means that adulteration and misbranding of the SynchroMed II device is controlled by Federal regulation, including CGMPs, and the device's PMA.

108. As stated in the 2006, 2006-2007, 2008-2009, and 2012 inspections and warning letters listed herein, the SynchroMed II Device was "adulterated under Section 501(h) of the Act [21 U.S.C. 351(h)], in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, found at Title 21, Code of Federal Regulations (CFR), Part 820."

109. Mr. Cline's SynchroMed II Device was then received in interstate commerce, was adulterated, and was delivered for pay or otherwise in violation of 21 U.S.C. §§ 331(c), 351(h) and 21 C.F.R. Part 820 and R.C. 3715.52 (3).

110. Mr. Cline's SynchroMed II Device was then adulterated while held for sale after shipment in interstate commerce in violation of 21 U.S.C. §§ 331(k), 351(h) and 21 C.F.R. Part 820 and R.C. 3715.52 (1).

111. Specific violations of CGMP regulations listed herein, rendered Mr. Cline's device, including his Device and second catheter, adulterated and misbranded in violation of 21 U.S.C. §§ 331(a), 351(h) and 21 C.F.R. Part 820 and R.C. 3715.52 (2). The adulteration and misbranding of Mr. Cline's device allowed for the production and sale of his device in a defective state. These defects resulted in a catheter which caused the formation of a granuloma around the area where the second catheter was placed and which caused the device to fail to properly deliver medication into his intrathecal space due to separation, occlusion, breakage, or other physical defect.

112. As a foreseeable, direct, and proximate result, the SynchroMed II Device implanted in Plaintiff's spine failed to deliver the prescribed medication as programmed, resulting in overdosing/underdosing and withdrawal from opiate medications as well as severe pain and failure to properly manage his pain. Additionally, due to defects in the second catheter and/or catheter connector, Mr. Cline has suffered a granuloma in the area of his spine where the second catheter meets with the spinal cavity causing Plaintiff to suffer injury and damages, including pain and suffering, lasting injury, mental anxiety and anguish, and medical bills.

COUNT II: Negligent Manufacturing Defect

113. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

114. Under Ohio law, "[a] product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards. A product may be defective in manufacture or construction as described in this section even though its manufacturer exercised all possible care in its manufacture or construction." Ohio Rev. Stat. § 2307.74.

115. Under Ohio law, the manufacture of a device is negligent where the formulation, production, construction, creation, assembly, testing, or marketing of the product caused the plaintiff's injury.

116. Under Ohio Rev. Stat. 3715.52, the following acts and causing them are prohibited: (1) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded; (2) The adulteration or misbranding of any food, drug,

device, or cosmetic; and (3) The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

117. The SynchroMed II Device is a Class III medical device, approved by the U.S. Food and Drug Administration (FDA) through the Premarket Approval (PMA) process on March 14, 1988, PMA No. P860004. This means that design specifications, formula, and performance standards are controlled by Federal regulation, including CGMPs, and the device's PMA.

118. The SynchroMed II Device implanted in Plaintiff's spine was manufactured in violation of the Federal Food, Drug, and Cosmetic Act and federal regulations promulgated pursuant thereto, and was manufactured in violation of CGMP requirements and Ohio law that parallels federal requirements. Each of these violations are described in Count I, as well as those other violations contained in this complaint.

119. Mr. Cline suffered direct and proximate damages due to the failures of Medtronic to properly manufacture, produce, construct, create, assemble, and/or test its pumps and catheters prior to sale because the device which Mr. Cline received was defective as manufactured and did not meet with CGMP standards or FDA PMA requirements. Specifically, as shown by the 2007 Warning Letter,²⁵ which found that Medtronic violated 21 C.F.R. § 806.10(a)(1) because a "correction or removal conducted to reduce a risk to health posed by a device was not reported in writing to FDA" concerning the risk of an inflammatory mass occluding intrathecal catheters and revealed several ongoing violations symptomatic of serious underlying problems in Medtronic's manufacturing and Quality Assurance systems.

120. Specific violations of CGMP regulations listed herein, rendered Mr. Cline's device, including his Device and second catheter, adulterated and misbranded in violation of 21 U.S.C. §§

²⁵ See *supra*, para. 48.

331(a), 351(h) and 21 C.F.R. Part 820 and R.C. 3715.52 (2). The adulteration and misbranding of Mr. Cline's device allowed for the production and sale of his device in a defective state. These defects resulted in a catheter which caused the formation of a granuloma around the area where the second catheter was placed and which caused the device to fail to properly deliver medication into his intrathecal space due to separation, occlusion, breakage, or other physical defect.

121. According to Mr. Cline's medical records, the SynchroMed II second catheter implanted into his body was defective in that it caused the formation of a granuloma around the area where the second catheter was placed and failed to properly deliver medication into his intrathecal space due to separation, occlusion, breakage, or other physical defect. The specifications of the SynchroMed II system indicate that it is intended, by the manufacturer, to deliver medication into the intrathecal space of the spine for the purposes of pain management. Mr. Cline's device was defective because it failed to perform this function, deviating from the specifications of the products design, formula, and/or performance standards in comparison to other SynchroMed II devices.

122. Medtronic produced a defective SynchroMed II Device which was then sold to and implanted in Mr. Cline. Medtronic's production of this defective device was caused and allowed by Medtronic's significant violations of Federal law including failure to comply with CGMP regulations and PMA specifications. The device which was sold to Mr. Cline was not the device which was approved by the FDA because it did not comply with the PMA specifications for that device and was produced in deviation from CGMP regulations.

123. As a foreseeable, direct, and proximate result, the SynchroMed II Device implanted in Plaintiff's spine failed to deliver the prescribed medication as programmed, resulting in overdosing/underdosing and withdrawal from opiate medications as well as severe pain and failure

to properly manage his pain. Additionally, due to defects in the second catheter and/or catheter connector, Mr. Cline has suffered a granuloma in the area of his spine where the second catheter meets with the spinal cavity causing Plaintiff to suffer injury and damages, including pain and suffering, lasting injury, mental anxiety and anguish, and medical bills.

COUNT II: Strict Liability Inadequate Warning or Instruction (R.C. § 2307.76)

124. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

125. Under Ohio law, R. C. 2307.76, a product is defective due to inadequate warning or instruction if, either during or post-marketing, “[t]he manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages,” or “[t]he manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.”

126. At all times relevant hereto, the Defendants intentionally, willfully, and/or recklessly, concealed material facts regarding risks associated with SynchrMed II Devices and catheters including those which caused Mr. Cline’s injuries and damages. Medtronic concealed this information from consumers and the medical and healthcare community, including Plaintiff and his providers, with respect to the SynchrMed II Device. A manufacturer exercising reasonable care would have provided consumers with information concerning the risks associated with SynchrMed II catheters, specifically the increased risk of developing a granuloma and the potential for kinking, occlusion, breakage, and other defects. This is especially true in light of the

likely harm to consumers, such as Mr. Cline, including severe pain and unintentional/unknown withdrawal from serious, potentially dangerous, medications.

127. Defendant represented that the SynchroMed II Device was safe and effective, free from defect, fit for use for its intended purpose, and that it met with all FDA PMA requirements and specifications under federal law. However, Mr. Cline's SynchroMed II device was defective as sold, caused the formation of a granuloma, and failed to deliver medication as programmed. This shows the SynchroMed II Device which Mr. Brumfield received was neither safe, nor effective, was unfit for its purpose to deliver medication as programmed, and that the Device did not comply with its PMA specifications.

128. At the time Defendants made these representations, Defendants knew the representations were false and misleading. The inspection and warning letters conducted in 2006-2007 directly reference several Federal violations related to catheter failures, in particular:

a. Medtronic violated 21 C.F.R. § 803.50(a)(1) through its "[f]ailure to submit MDR reports within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury."

b. Medtronic failed to report SynchroMed II Device's intrathecal catheters associated with granuloma or inflammatory masses at or near the distal tip, which the FDA considers "serious injuries;"

c. Medtronic failed to report SynchroMed II Device's intrathecal catheter fractures;

d. Medtronic failed to report a malfunction MDR, required when a marketed device malfunction would likely cause or contribute to a reportable death or serious injury;

e. Medtronic failed to submit MDR reports within 30 days of learning of a problem (Device malfunctions, catheter fracture or separation, inflammatory masses and granulomas) with the SynchroMed II device in the medical literature; and

f. Medtronic failed to report consumer self-reported adverse events.

129. These failures, as documented, show that Medtronic was fully aware of the increased risk and serious injuries associated with catheter fractures, malfunctions, separations, and the potential for inflammatory masses and granulomas because they were reported to Medtronic, stated by the FDA, and continued over a long period of time.

130. This is further supported by the 2007 Warning Letter, followed by recall no. Z-1150-2008, which found that Medtronic violated 21 C.F.R. § 806.10(a)(1) because a “correction or removal conducted to reduce a risk to health posed by a device was not reported in writing to FDA” concerning the risk of an inflammatory mass occluding intrathecal catheters and revealed several ongoing violations symptomatic of serious underlying problems in Medtronic’s manufacturing and Quality Assurance systems.

131. In 2013, FDA found that Medtronic violated 21 C.F.R. § 806.10(a)(1) because a “correction or removal conducted to reduce a risk to health posed by a device was not reported in writing to FDA” concerning the risk of an inflammatory mass occluding intrathecal catheters. The FDA also issued a Form 483 against Medtronic for then distributing nonconforming catheters, prone to occlusion, and for failure to implement recommendations from the Risk Evaluation Board, “Health Hazard Assessments for high priority CAPAs with the highest patient severity of death were not completed in a timely fashion,” and “Health Hazard Assessments have not been updated after CAPA effectiveness monitoring signaled an increase in the rate of occurrence” of hazards involving intrathecal catheter occlusion.

132. These facts clearly show that Medtronic knew the risks associated with SynchroMed II catheters, including the one sold to Mr. Cline, and that these risks caused harm, including the harm suffered by Mr. Cline, and Medtronic failed to provide additional warning or instruction equal to the seriousness of the harm under which this claim is brought.

133. Plaintiff did not modify or alter the SynchroMed II Device or second catheter in any way and used it as intended or within a reasonably foreseeable way.

134. As shown above, and as detailed in Count I, Mr. Cline's second catheter clearly did not comply with its PMA specifications in that it was defective due to motor stall. It was manufactured in violation of CGMP regulations. As such, Mr. Cline's catheter did not comply with the design and manufacturing standards approved by the FDA for this device.

135. Additionally, Mr. Cline's SynchroMed Device was a misbranded product, for the purposes of 21 C.F.R. § 808.1(d)(6), because it failed to conform to approved labeling in that it failed after four years of use when it was intended to last seven years, according to Medtronic's representations and the specifications in the PMA.

136. Mr. Cline was also directly and proximately injured due to Medtronic's marketing of the product which represented the SynchroMed II Device system as a safe and effective alternative to oral medications because, even with the device implanted, due to the defective Device and second catheter, Mr. Cline was required to take additional oral medications to manage his condition.

137. Defendants are and were under a continuing duty to monitor and disclose the risks of the SynchroMed II device. They have fraudulently concealed the risks and their knowledge of them. Defendants' fraudulent concealment was designed to prevent, and did prevent, the public and the medical community at large from discovering the risks and dangers associated with the

SynchroMed II device. Their fraudulent concealment also prevented Plaintiff from discovering, and/or with reasonable diligence being able to discover his cause of action.

138. Medtronic failed to properly warn Mr. Cline of the dangers of its defective products prior to implantation and failed to adequately warn the public about its knowledge of the serious and long term history of defects in its products. Mr. Cline was directly and proximately harmed by this failure because, had he been aware of the dangers of the SynchroMed II Device and catheters, including their propensity to stall, overinfuse/underinfuse medication, kink/occlude, become disconnected, and otherwise fail, Mr. Cline would not have chosen to receive the implanted Device and catheter system.

139. Plaintiff claims that his particular SynchroMed II device was defective for failure to provide adequate warnings because his individual device was defective. As such, the warnings and instructions provided by Medtronic did not properly inform Mr. Cline of the risk of granuloma, cessation of therapy, or withdrawal due to defects in the device of which Medtronic was, and had been aware, for a very long time. Plaintiff alleges this claim for breach of Medtronic's duty under state law to warn of potential risks based on information obtained subsequent to FDA approval of the SynchroMed II Device, specifically the information regarding the catheter, occlusion, granuloma, and cessation of therapy.

140. As a foreseeable, direct, and proximate result, the SynchroMed II Device implanted in Plaintiff's spine failed to deliver the prescribed medication as programmed, resulting in overdosing/underdosing and withdrawal from opiate medications as well as severe pain and failure to properly manage his pain. Additionally, due to defects in the second catheter and/or catheter connector, Mr. Cline has suffered a granuloma in the area of his spine where the second catheter

meets with the spinal cavity causing Plaintiff to suffer injury and damages, including pain and suffering, lasting injury, mental anxiety and anguish, and medical bills.

**COUNT III: Breach of Implied Warranty of Merchantability (R.C. 1302.27 & 1302.28
(UCC 2-314 & 2-315))**

141. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

142. Under Ohio law, a defendant violates the implied warranty of merchantability under Ohio Rev. Stat. § 1302.27 (UCC 2-314) when goods are not merchantable the time they are sold. To be merchantable, goods must, among other things, be of fair, average quality within the description, fit for the ordinary purpose for which such goods are used, and be of even kind, quality and quantity, within each unit and among all units involved.

143. Under Ohio law, a defendant violates the implied warranty of fitness for a particular purpose under Ohio Rev. Stat. § 1302.28 (UCC 2-315) when “the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods” and such goods fail to function for that particular purpose for which they are sold.

144. The SynchroMed II device sold to Plaintiff was not merchantable because the manufacture and sale of the device violated federal law in that the device was adulterated and misbranded at the time it was sold, as described in Count I, Strict Liability Manufacturing Defect.

145. The SynchroMed II device sold to Plaintiff was not fit for the particular use for which it was sold because it failed to manage his pain, failed to deliver medication as programmed into the intrathecal space of his spine, and caused him to develop a granuloma. Defendant was fully aware of the particular purpose for which Mr. Cline was purchasing the SynchroMed II

Device and that Mr. Cline was relying on Medtronic's representations of safety and efficacy, as described fully in Count II, Strict Liability Inadequate Warnings or Instructions.

146. At all times relevant, Defendants, and each of them, made misrepresentations and omissions of material facts, in violation of Ohio Rev. Stat. § 2307.77 and other laws, statutes, and codes, including but not limited to the following:

- a. That Plaintiff's implant was fit for its intended use;
- b. That Plaintiff's implant was of merchantable quality;
- c. That Plaintiff's implant was safe and effective for the treatment of Plaintiff's condition;
- d. That Plaintiff's implant would function as intended;
- e. That Plaintiff's implant was not defective, such that it would fail to function as intended; and
- f. That Plaintiff's implant was not unreasonably dangerous.

147. At all times relevant, these representations and omissions were false and misleading at the time they were made.

148. At all times relevant, Defendants, and each of them, negligently, carelessly, recklessly, and/or otherwise made the foregoing misrepresentations of fact.

149. At all times relevant, Defendants, and each of them, made misrepresentations of fact even though they knew or should have known the statements to be false.

150. In reliance upon the misrepresentations made by the Defendants, and each of them, Plaintiff was induced to and did subject himself to the use of the product. If Plaintiff had known the true facts, he would not have taken such action and risk. Plaintiff's reliance on Defendants'

misrepresentations was reasonable as said representations were made by individuals and entities in a position to know the true facts.

151. As a foreseeable, direct, and proximate result, the SynchroMed II Device implanted in Plaintiff's spine failed to deliver the prescribed medication as programmed, resulting in overdosing/underdosing and withdrawal from opiate medications as well as severe pain and failure to properly manage his pain. Additionally, due to defects in the second catheter and/or catheter connector, Mr. Cline has suffered a granuloma in the area of his spine where the second catheter meets with the spinal cavity causing Plaintiff to suffer injury and damages, including pain and suffering, lasting injury, mental anxiety and anguish, and medical bills.

COUNT IV: Punitive Damages (R.C. § 2315.21(C)(1))

152. Plaintiff incorporates by reference as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

153. Defendants knew or should have known that the SynchroMed II Device was defective and presented an unreasonable risk of harm to Plaintiff.

154. Defendants' conduct as described in this Complaint, for which Plaintiff is entitled to recover compensatory damages, manifested the entire want of care such that it demonstrated a conscious indifference to, flagrant disregard of, and malice towards the safety of those persons who might foreseeably have been harmed by the SynchroMed II Device, including Plaintiff, justifying the imposition of punitive damages under Ohio Rev. Code § 2315.21(C)(1).

VI. CONCLUSION

WHEREFORE, Plaintiff prays for the following:

- (a) That Plaintiff recover from Defendants, jointly and severally, general and special damages, all in an amount to be determined by a jury of Plaintiff's peers;
- (b) That Plaintiff recover against Defendants for their wrongful conduct such punitive damages that will punish and deter similar conduct, all in an amount to be determined by a jury of Plaintiff's peers;
- (c) That Plaintiff recover reasonable attorneys' fees and expenses of litigation; and
- (d) That Plaintiff has such other and further relief as this Honorable Court deems just and proper under the circumstances.

RESPECTFULLY SUBMITTED,

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